K121089

510(K) SUMMARY

AUG 23 2012

Date prepared: July 24, 2012

A. Sponsor

Navilyst Medical, Inc
26 Forest Street
Marlborough, MA 01752

B. Contact

Lorraine M. Hanley
Vice President, Global Regulatory Affairs
508-658-7945
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C. Device Name

Trade Name:	NMI PICC III
Common/Usual name:	Peripherally Inserted Central Catheter (PICC)
Classification Name:	Short and Long-Term Intravascular Catheter 21CFR§880.5970, Class II
Classification Panel:	General Hospital

D. Predicate Device(s)

Common/Usual name:	Peripherally Inserted Central Catheter (PICC)
Classification Name:	Short and Long-Term Intravascular Catheter 21CFR§880.5970, Class II
Premarket Notification(s):	K070002, K101326, K091261, K093366, K083763

E. Device Description

The NMI PICC III are flexible radiopaque catheters with suture wing for catheter securement, extension tubes(s) which connect to proximally located luer lock adapter(s) with and without a pressure activated safety valve (PASV), available in single lumen and multi-lumen configurations and a reverse tapered shaft to aid in staunching bleeding at the insertion site.

The lumens are differentiated by proximally located colored extension tube clamps and/or colored luer adaptors, which identify lumen size, if the lumen is rated for power injection the maximum power injection flow rates, and "NO CT" for non-power injectable lumens.

All NMI PICC III models have been designed with the option of being used with power injectors for the administration of contrast media for imaging studies such as Computerized Tomography (CT) scans and Magnetic Resonance Imaging (MRIs). Models with at least one non-valved lumen are also indicated for central venous pressure monitoring. All catheters are available packaged with a variety of procedural accessories as a convenience to suit specific clinician preference that meet the needs of the PICC placement practice at their institution and in standard kit configurations.

Endexo technology has been shown to be effective in reducing thrombus accumulation. Reduction of thrombus accumulation was evaluated using in vitro and in vivo models. Pre-clinical in vitro and in vivo evaluations do not necessarily predict clinical performance with respect to thrombus formation.

F. Intended Use

The NMI PICC III is indicated for short- or long-term peripheral access to the central venous system for intravenous therapy, including but not limited to, the administration of fluids, medications and nutrients, the sampling of blood, for central venous pressure monitoring and for power injection of contrast media.

Maximum Power Injection Flow Rate

Description	Flow Rate
4F Single Lumen – 55cm length	3.5 mL/sec
5F Single Lumen – 55cm length	5 mL/sec
5F Dual Lumen – 55 cm length	4 mL/sec
6F Dual Lumen – 55cm length	5 mL/sec

The NMI PICC III with PASV Valve Technology is indicated for short- or long-term access to the central venous system for intravenous therapy, including but not limited to, the administration of fluids, medications and nutrients, the sampling of blood, and for power injection of contrast media.

Maximum Power Injection Flow Rate

Description	Flow Rate
3F Single Lumen – 55cm length	1 mL/sec
4F Single Lumen – 55cm length	3.5 mL/sec
5F Single Lumen – 55cm length	5 mL/sec
5F Dual Lumen – 55cm length	4 mL/sec
6F Dual Lumen – 55cm length	5 mL/sec
6F Triple Lumen – 55cm length	6 mL/sec

G. Summary of Similarities and Differences in Technological Characteristics and Performance

The proposed device has similar materials, design and components and technological characteristics as predicate intravascular catheters.

Both the NMI proposed and predicate devices are,

- in brief, intended for short and long-term peripheral access to the central venous system for intravenous therapy, blood sampling, and power injection of contrast media,
- available in single- and multi-lumen configurations in a wide range of sizes from 3 to 6 Fr outside diameter,
- rated for maximum power injector settings up to 325 psi with maximum power injection flow rate up to 6 ml/second based on model, and
- available kitted with a range of procedural accessories for user convenience.

When compared to currently marketed PICCS, the proposed NMI PICC III has demonstrated enhanced resistance to blood component (platelet and thrombus) accumulation.

H. Performance Data

The performance evaluation of the NMI PICC III included testing conducted in accordance with the following FDA guidance document and international standards:

- EN ISO 10555-1:2009, *Sterile, Single use intravascular catheters – Part 1: General Requirements*
- EN ISO 10555-3:1997 Corrigendum 1:2002, *Sterile, Single-Use Intravascular Catheters – Part 3: Central Venous Catheters*
- FDA's "*Guidance on Premarket Notification [510(K)] Submissions for Short-Term and Long-Term Intravascular Catheters dated March 16, 1995*"
- Biocompatibility per ISO 10993-1.

The proposed NMI PICC III successfully passed testing including:

- Internal Product Specification Requirements
- Luer Connection / Strength
- Power Injection
- Valve Integrity
- Catheter Interface Compatibility
- Central Venous Pressure Monitoring
- Chemical / Vesicant Compatibility
- In-Vitro 2 hour blood loop thrombus reduction testing to quantify the relative thrombogenic potential of the NMI PICC III in comparison to commonly used PICC's.
- In Vivo study evaluating the thromboresistance of the NMI PICC III compared to a heparin-based thromboresistant control catheter during both 14 and 31 day indwelling times in an ovine model.

I. Conclusion

Results of testing according to recognized standards, and in-vitro and in-vivo testing, and in consideration of the responses to questions posed in FDA's 510(k) Decision Making Tree, the proposed device is determined to be substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 2 3 2012

Navilyst Medical, Inc.
C/O Lorraine M. Hanley
VP Global Regulatory Affairs
26 Forest Street
Marlborough, Massachusetts 01752

Re: K121089
Trade/Device Name: NMI PICC III
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, implanted, long-term intravascular catheter
Regulatory Class: II
Product Code: LJS
Dated: July 24, 2012
Received: July 25, 2012

Dear Ms. Hanley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

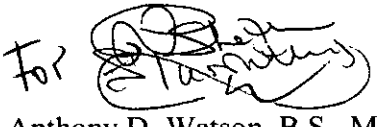
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
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Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if Known): K121089

Device Name: NMI PICC III

Indications for Use:

NON-VALVED VERSION

The NMI PICC III is indicated for short- or long-term peripheral access to the central venous system for intravenous therapy, including but not limited to, the administration of fluids, medications and nutrients, the sampling of blood, for central venous pressure monitoring and for power injection of contrast media.

Maximum Power Injection Flow Rate:

•4F Single Lumen/55 cm – 3.5 mL/sec

•5F Single Lumen/55 cm – 5 mL/sec

•5F Dual Lumen/55 cm – 4 mL/sec

•6F Dual Lumen/5 cm – 5 mL/sec

VALVED VERSION

The NMI PICC III with PASV Valve Technology is indicated for short- or long-term peripheral access to the central venous system for intravenous therapy, including but not limited to, the administration of fluids, medications and nutrients, the sampling of blood and for power injection of contrast media.

Maximum Power Injection Flow Rate:

•3F Single Lumen/55 cm – 1 mL/sec

•4F Single Lumen/55 cm – 3.5 mL/sec

•5F Single Lumen/55 cm – 5 mL/sec

•5F Dual Lumen/55 cm – 4 mL/sec

•6F Dual Lumen/55 cm – 5 mL/sec

•6F Triple Lumen/55 cm – 6 mL/sec

Prescription Use ☒ And/Or AND/OR Over-The-Counter Use: ☐

(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

8/22/12

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K121089